CHAPTER 3

High-Cost Medicines in England

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3.1 INTRODUCTION

The Constitution of the UK's National Health Service (NHS) states that the health system will provide a comprehensive service, available to all, with access based upon clinical need and not individual ability to pay (DoH, 2015). At the same time, the system is committed to providing best value for taxpayers' money. The recent growth in the availability of 'high-cost medicines' has challenged the UK government's commitment to providing a comprehensive service, free at the point of delivery, when doing so has a substantial impact upon public expenditure. Most NHS services are funded through general taxation, with funds being allocated to providers primarily through the route of local contracting for services by Clinical Commissioning Groups (CCGs) (NHS England, 2017). Under the current arrangements, all medicines supplied by the NHS are reimbursed by the health system with funds initially provided by the Department of Health (DoH) on behalf of the UK government.

Prescribing spends in both primary and secondary cares are reimbursed nationally from money raised from general taxation and distributed by the DoH. Overall, NHS spending on medicines in 2015/2016 was £15.8 billion (NHS Digital, 2016). Hospital prescribing was 54.2% (£7.6 billion) of this total, with the rest (£9.0 billion) being spent in primary care. In recent years, there has been the rapid growth in spending on drugs by hospitals, which increased from £4.2 billion in 2010/2011 to £7.6 billion in 2015/2016, a rise of 81.8%. This growth was caused by the introduction of new and innovative medicines, as well as the greater use of specialist drugs. Positive technology appraisals by The National Institute for Health and Care Excellence (NICE) have also placed pressure on the nation's drugs bill. For instance, Adalimumab for auto-immune conditions cost the NHS £416.6 million in 2015/2016, with £391.1 million being spent in secondary care.

In 2016, the cost of prescription dispensed by community pharmacies in England was just over £9.20 billion (NHS Digital, 2016). The average cost

Equitable Access to High-Cost Pharmaceuticals
http://dx.doi.org/10.1016/B978-0-12-811945-7.00003-8
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per item was £8.34 (£9,204,891,304/1,104,131,794 items). When receiving their medicines, some patients must pay a co-payment called the 'prescription charge' for each item dispensed (Baines, 2013a). Set at a rate of £8.60 from April 2017, the charge is slightly higher than the average cost per item dispensed. Although this seems like a positive balance, nearly 90% of all prescriptions are dispensed free of charge. In relation to high-cost medicines, patient age and the severity of illness means that most people receiving this class of drugs are usually exempt or choose to pre-paid the charge at a discounted rate. Even if patients are obliged to pay the fee, the amount does not increase with the price of the pharmaceuticals required. Therefore, the prescription charge does little to cover the costs of high-cost medicines supplied.

Prescriptions dispensed in the community are reimbursed by the Prescription Pricing Authority at agreed national rates (Baines, 2014a). In contrast, hospitals receive income for providing predefined packages of patient care that are reimbursed as part of the 'NHS tariff'. Drugs supplied in secondary care must be purchased and paid for by the hospitals themselves with the income generated providing patient services and payments received from NHS England. Consequently, the price for community-dispensed drugs is set nationally, whereas large variations in medicine prices between hospitals is common, particularly in relation to high-cost drugs. Both the variation and the growth of prices of high-cost drugs are issues of current concern to NHS policy-makers and the UK government.

The purpose of this chapter is to provide an overview of NHS policy to control public expenditure on high-cost drugs. As Scotland, Wales and Northern Ireland have devolved powers that cover the operation of their health services, the chapter will focus on policies and institutional structures in England. The chapter is written from the health service point of view, with an emphasis on existing measures designed to assist NHS decision-makers in dealing with pressures on its cash-limited hospital and primary care budgets. To analyse current policy, the following tasks are performed. First, background to the current policies for controlling high-cost drugs is provided. Second, arrangements and policies for controlling high-cost drugs are analysed. Third, the way ahead is discussed. The chapter closes with conclusions.

3.2 BACKGROUND

The NHS has been forced to manage ever-increasing drugs costs since the system was first introduced in 1948. This section discusses past and current approaches to prescribing cost control that affect the ways in which

high-cost drugs are currently managed. These include: Policy in history; National arrangements; NICE guidance; The Carter Review.

3.2.1 Policy in History

Since its inception in 1948, the NHS has struggled to contain the nation's drugs bill. The introduction of healthcare, free at the point of delivery, stimulated an unprecedented demand for a wide range of available treatments, particularly medicines (Baines, 2013b). During the early years of the NHS, Regional Medical Officers would visit high-cost prescribers to discuss their medicines spends. Sanctions could only be applied if evidence suggested that over-prescribing had occurred at the level of an individual patient. Spending significant amounts on one product, or using high-cost drugs, were not grounds for investigation. This approach continued until the early-1990s, when the incumbent Conservative government introduced prescribing budgets into general practice (Baines et al., 1997a). From that time onwards, high-cost prescribing was defined in terms of total practice spends compared with local, regional and national averages. Spend was also judged in terms of out-turns against budgets set. Again, expenditure on individual or high-cost products was not a concern unless the result was significant overspends (Baines et al., 1997b). Not until very recently has the health service judged high-cost prescribing in terms of the price of individual medicines.

3.2.2 National Arrangements

In 2017/2018, planned spending for the DoH in England is approximately £123.7 billion (Charlesworth et al., 2017). The DoH leads the NHS by creating national policies and legislation, funding the service and assuring the delivery of services to Parliament. The DoH also leads on the Pharmaceutical Price Regulation Scheme (PPRS), which limits overall NHS spending on branded drugs (Baines, 2014b; DoH, 2016). This arrangement does not include special regulations for high-cost drugs and manufacturers are free to set their own prices. NHS England is an executive non-departmental pubic body of the DoH, which oversees the budget, planning, delivery and day-to-day operation of the NHS in England. Therefore, NHS England must deliver DoH policies on high-cost drugs. Within this framework, NICE appraises the clinical and cost-effectiveness of new drugs and recommends which should be routinely funded by the health service. NHS England assesses whether to approve funding for high-cost drugs and devices not approved by NICE. The DoH's Commercial Medicines Unit currently

manages the frameworks for drug purchasing, whilst controlling demand for individual products is an NHS England responsibility.

3.2.3 NICE Guidance

The NICE Technology Appraisal process assesses the clinical and cost-effectiveness of new and existing medicines and provides guidance on their use by the NHS (Cowles et al., 2017). Three quarters of NICE technology appraisals affect provision by specialist services. Under current regulations, NHS bodies are legally required to fund NICE guidance within 90 days (NHS England Cancer Drugs Fund Team, 2016). Table 3.1 shows the cost implications of 20 recent NICE guidelines that have had the greatest impact on health service spends. As shown, the impact of a positive NHS appraisal on expenditure can be both rapid and significantly large. As the data suggests, NICE does not always consider affordability when approving high-cost drugs. However, the body adopted a more thoughtful approach for the introduction of a new Hepatitis C treatment by enabling NHS England to adopt a phased approach to its adoption (NHS England, 2015). In response, The Hepatitis C Trust has filed Court proceedings challenging the adoption of this delayed approach. In recent years, NICE recommendations have driven a substantial proportion of the annual uplift in spending by the NHS on specialist services. Once a NICE guideline is issued, all health service providers, including specialist teams, have a legal duty to follow its recommendations within three months. Therefore, NICE is a cost-driver that, in many instances, increases NHS spends on expensive medicines.

3.2.4 The Carter Review

Published in June 2015 and updated in February 2016, Lord Carter's review of efficiency in NHS acute hospitals in England found that significant improvements in productivity could be achieved, which could reduce the unwarranted variations in performance between providers (Lord Carter, 2016). In relations to medicines, the Carter Review found significant differences in total pharmacy and drug costs across acute trusts. Although some of the variance was related to teaching status or the provision of specialist services, Lord Carter found that savings of £800 million on medicines spends were available. To this end, the report recommended that hospital trusts should: (1) Through a Hospital Pharmacy Transformation Programme (HPTP), develop plans to ensure hospital pharmacies achieve specified productivity benchmarks; (2) ensure their HPTP plans include a review of services not

Table 3.1 Overall Top 20 Medicines by Estimated Prescribing Cost for Medicines Positively Appraised by NICE Prescribed or Issued in All Sectors in 2015/2016

Medicine	Most Recent TA	Condition	Sector Where Highest Cost is Incurred	Total Cost (£000's)
Adalimumab	TA383—February 2016	TNF–alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis	Secondary care	416,647.8
Ranibizumab	TA298—November 2013	Choroidal neovascularisation associated with pathological Myopia	Secondary care	248,975.9
Etanercept	TA383—February 2016	TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis	Secondary care	230,588.3
Aflibercept (solution for injection)	TA346—July 2015	Treating diabetic macular oedema	Secondary care	198,268.4
Infliximab	TA375—January 2016	Rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed	Secondary care	178,179.2
Rituximab	TA308—March 2014	Anti-neutrophil cytoplasmic antibody-associated vasculitis	Secondary care	155,893.3
Trastuzumab	TA208—November 2010	HER2-positive metastatic gastric cancer	Secondary care	152,037.6
Lenalidomide	TA322—September 2014	Treating myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality	Secondary care	141,840.4
Rivaroxaban	TA335—March 2015	Preventing adverse outcomes after acute management of acute coronary syndrome	Primary care	106,586.8
Imatinib	TA326—November 2014	Adjuvant treatment of gastrointestinal stromal tumours	Secondary care	89,067.7

(*Continued*)

Table 3.1 Overall Top 20 Medicines by Estimated Prescribing Cost for Medicines Positively Appraised by NICE Prescribed or Issued in All Sectors in 2015/2016 (*cont.*)

Medicine	Most Recent TA	Condition	Sector Where Highest Cost is Incurred	Total Cost (£000's)
Enzalutamide	TA377—January 2016	Treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated	Secondary care	86,360.4
insulin glargine	TA053—December 2002	Type 1 and Type 2 Diabetes	Primary care	81,629.9
Ledipasvir-sofosbuvir	TA363—November 2015	Treating chronic hepatitis C	Secondary care	81,054.7
buprenorphine (excluding combination with naloxone)	TA114—January 2007	Drug misuse	Primary care	76,728.9
Abiraterone	TA259—June 2012	Treatment of castration-resistant metastatic prostate cancer previously treated with one docetaxel-containing regimen	Secondary care	74,148.7
Sofosbuvir	TA330—February 2015	Treating chronic hepatitis C	Secondary care	73,443.0
tacrolimus (immuno-suppression-oral)	TA099—April 2006	Renal Transplant	Secondary care	71,435.0
Docetaxel	TA109—September 2006	Breast cancer (early)	Secondary care	66,654.8
Dimethyl fumarate	TA320—August 2014	Treating relapsing remitting multiple sclerosis	Secondary care	64,178.5
Paclitaxel	TA55—January 2003	Treatment of ovarian cancer	Secondary care	61,298.3

Source: NHS Digital (2016). Provided under the terms of the Open Government Licence v3.0.

currently outsourced and have a plan in place for improving productivity and efficiency, including consideration of alternative supply routes, such as homecare providers or community pharmacies; (3) seek to reduce their medicines bill through best choices and from actively monitoring market developments, such as the launch of biosimilar products; (4) task their finance director, working with their chief pharmacist, to ensure that the coding of medicines, particularly high-cost drugs, are accurately recorded; and (5) identify the true value and scale of opportunities for rationalisation and integration of hospital pharmacy procurement and production. These recommendations set the requirements for medicines optimisation within English acute hospitals. They form the background against which current NHS policy for managing the use of high-cost drugs should be judged.

3.3 HIGH-COST DRUGS

Because of their nature, the initial decision to prescribe high-cost drugs is often made in secondary care, usually within specialist services and often funded by the NHS Cancer Fund. This section discusses these arrangements and provides an overview of current NHS policy for high-cost drugs, including an outline of a recent Commission for Quality and Innovation (CQUIN) payment for optimising the use of medicines in hospitals.

3.3.1 Specialised Services

Specialised services are provided in a small proportion of NHS hospitals for patients with rare conditions or individuals who need care from a specialised team (NHS England, 2016a). There are 146 services classified as 'specialised', which covers a wide range of complex interventions. These include treatments for long-term conditions (such as renal and mental health problems) to services for uncommon conditions such as rare cancers. Some specialised services (such as those for cystic fibrosis) cover all patient care. However, most specialised services only form a part of a patient's treatment pathway. A very small number of highly specialised services (including those for very rare diseases) are only provided in one or two centres across England. Others (such as chemotherapy services) are provided by most acute hospitals.

In April 2013, NHS England took responsibility for commissioning specialised services. Through its commissioning of these services, NHS England aims to: (1) Improve outcomes for patients; (2) ensure patients have equal access to services; and (3) improve productivity and efficiency. Like the objectives of the NHS Constitution, these commissioning aims for

specialised services also embody a tension between the desire to provide patients with the effective medicines they need and the ability of cash-limited NHS budgets to supply them. Nowhere else in the health service is this conflict of aims more apparent than with high-cost drugs funded by specialised services. Budget out-turns since NHS England took over commissioning clearly tells the story. Between 2013/2014 and 2015/2016, the allocation for specialised services increased from £13 billion to £14.6 billion, an average annual increase of 6.3%. Over this period, the total NHS budget increased by 3.5% per average year. By 2020/2021, the allocation for specialist services is expected to rise to £18.8 billion, which will be 16% of the total NHS budget.

Even with a rapidly growing allocation, NHS England has found it challenging to live within its budget for specialised services. In 2013/2014, the overspend was £377 million. In 2014/2015, £214 million was overspent, with the Cancer Drugs Fund accounting for £136 million of this amount. In 2015/2016, high-cost drugs constituted about £3 billion of the total spend by NHS specialised services, and estimates for the future suggest that this amount will continue to grow. Given the current arrangements for managing high-cost drugs—such as NICE's role in recommending new treatments—NHS England has little control over the drivers of the rising spends on high-cost drugs by specialist providers.

3.3.2 Cancer Drugs Fund

Survival rates for cancer patients in England have generally been worse than those in other high-income countries in Europe, mainly because patients in England are diagnosed later and have poorer access to treatment (Grieve et al., 2016). The government set up the Cancer Drugs Fund in 2010 to improve access to cancer drugs. In the last five years, approximately 80,000 people received their medicines through the Fund, which grew from £175 million in 2012/2013 to £416 million in 2014/2015 (an increase of 138% over two years). In the years 2013/2014 and 2014/2015, NHS England overspent the Fund's £480 million budget by £167 million. NHS England did not act to control the growth in costs until November 2014, by which time 39 cancer drugs, covering 67 different licensed uses, were available through the Fund. Currently, there is general agreement that NHS England in consultation with NICE must improve the way in which the scheme is managed.

In January 2016, the House of Commons Committee of Public Accounts published a report on the operation of the Cancer Drugs Fund

(House of Commons Committee of Public Accounts, 2016). The report concluded that the DOH and NHS England: (1) Have not managed the Fund effectively; (2) are not using their buying power effectively to pay fair prices for cancer drugs; (3) do not have data to evaluate the impact of the Fund on outcomes for patients; (4) have not reduced regional variations to secure equal access between areas to the Fund; (5) have failed to support NICE develop its capacity to evaluate all new cancer drugs; and (6) have not improved survival rates for cancer patients to international standards. In response to these failings, the Public Accounts Committee recommended that: (1) NHS England should set clear objectives for the Fund, and be prepared to take tough decisions to ensure that the Fund does not overspend; (2) the DoH should outline how it ensures that fair prices for drugs are paid, and specify what lessons that can be drawn from the Fund's negotiations with pharmaceutical companies about drug pricing; (3) NHS England should provide data on the impact of the Fund on patient outcomes; (4) NHS England should analyse the extent of regional variation in access to the Fund, and outline plans to ensure that access is fair across the country; (5) NHS England should assess whether NICE has the capacity to appraise all new cancer drugs; and (6) NHS England should implement a clear plan to ensure that the NHS has sufficient diagnostic capacity, including appropriately trained staff, to improve early diagnosis of cancer. Currently, these recommendations are changing the ways in which the DoH and NHS England manage the Cancer Drugs Fund, which will soon have an impact on the commissioning (and spending) on high-cost drugs.

3.3.3 Hospital Medicines Optimisation

Throughout England, many NHS acute providers spend significantly on high-cost drugs. In response, the NHS recently launched a new CQUIN designed to support procedural and cultural changes in hospitals to fully optimise the use of medicines commissioned by specialised services (NHS England, 2016b). For instance, ensuring that hospitals have HPTP plans that reflect the NHS England priorities of improving value for money in medicines procurement and reducing unwarranted variation in high-cost drug spends. The CQUIN funds additional pharmacy staff to help achieve these end and to ensure that each HPTP plan is supported at Trust Board level. The funding assumes that one (whole time equivalent) pharmacist plus admin/analytical support is required for every £25 million of drugs expenditure. This extra staff time must be used to optimise the use of medicines and to help generate some of the savings identified by the Carter Review.

CQUIN funds are designed to deliver better outcomes in the following priority areas: (1) Faster adoption of best value medicines with a focus on generics and biologics; (2) significantly improved drugs data to include appropriate coding; (3) the consistent application of the lowest cost dispensing channels; and (4) compliance with policy/consensus guidelines to reduce variation and waste. The CQUIN is one of the first actions linked to the government's plans to rationalise medicines use and purchasing in NHS acute hospitals, particularly in relation to high-cost drugs.

3.4 THE WAY AHEAD

In July 2016, the House of Commons Committee of Public Accounts published a report on NHS specialised services. The report concluded that NHS England does not have a clear plan for configuring and delivering this type of NHS care. Moreover, a lack of transparency over NHS England's decision-making is undermining accountability to both patients and taxpayers. To add to its problems, NHS England has not overcome barriers to collaborative commissioning with CCGs and lacks information on costs, access and outcomes necessary to improve existing provision. In short, significant improvements are required. Importantly, many of the planned reforms of specialist services (the Cancer Drugs Fund) that will occur in coming years will have a direct impact on the accessibility to and spending on high-cost drugs. In particular, higher prices may be challenged, lower volumes prescribed and regional variations addressed.

The analysis performed in this chapter suggests that the NHS is at a turning point in the ways in which high-cost drugs are managed and funded. In recent years, costs have grown beyond what the Public Accounts Committee, the DoH and NHS England believe acceptable. The response will be a concerted attempt to produce joined-up policies that encourage acute hospitals and specialist service providers to optimise medicines use, whilst pursuing greater value for money in drug purchasing. Whilst NHS England is tasked with better managing specialist services and reducing high-cost drug spends, the question remains of what is achievable within the current framework. High-cost drugs are relatively expensive because of the high costs of developing and launching new clinical entities. Whilst some commentators believe that new medicine prices are not justifiable, high-cost drugs are, an international phenomenon. Beyond price negotiations with manufacturers, the only real solution to the extra expenditure that they generate is the rationing of access to the latest pharmaceutical technologies. In systems such

as the NHS, high-cost drugs create a real tension between the objectives of meeting patient needs and securing value for money for tax-payers. Whatever policy initiatives are implemented, the conflict between need and affordability cannot be easily resolved. For real change to occur, either drug prices must drop significantly or a new remit may be required for NICE that focuses less on clinical and cost effectiveness and deals directly with affordability and budget out-turns. Whatever road is taken, high-cost drugs will remain a real challenge for NHS decision-makers, particularly as recent policy recommendations have yet to prove themselves in practice. In coming years, failure to control the growing spend on such medicines may eventually limit the ability of NHS England to fund care for patients outside of specialised services. Therefore, high-cost drugs is an issue of concern that directly challenges the viability of the NHS as currently constituted.

3.5 CONCLUSIONS

High-cost drugs are proving a challenge for many healthcare systems worldwide. Currently, arrangements for managing spends on these products are currently being reviewed and reformed for the NHS in England. With a clear focus on cost control, a consequence of ongoing policy changes may be reduced access to high-cost medicines. In coming years, close monitoring and objective evaluation will be required to analyse the effect of the current policy on patients and taxpayers, with an inevitable trade-off between spending and access driving the outcomes observed.

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